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U.S. DISTRICT COURT
DISTRICT OF MASS.

January 9, 2004

VIA HAND DELIVERY

Clerk's Office
United States District Court
District of Massachusetts
One Courthouse Way, Suite 2300
Boston, Massachusetts 02210

Re: In Re: Pharmaceutical Industry Average Wholesale Price Litigation,
MDL No. 1456, Civil Action No. 1:01-CV-12257-PBS
State of California, et al. v. Abbott Laboratories, Inc., et al.,
Civil Action No. 1:03-CV-11226-PBS

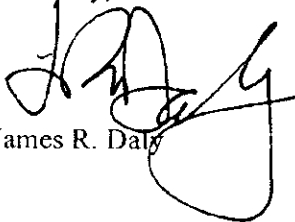
Dear Sir or Madam:

Enclosed for filing in the above-captioned matter, please find the following:

**Abbott Laboratories, Inc.'s Response To The State Of California's
Supplemental Brief Regarding Remand And Federal Preemption Of Rebate
Claims**

Please acknowledge this filing by date-stamping the enclosed copy of this letter and returning it to the waiting messenger. Thank you for your assistance.

Sincerely,



James R. Daly

Enclosure

cc: All Counsel of Record In Re: Pharmaceutical Industry Average Wholesale Price
Litigation, MDL No. 1456, Civil Action No. 1:01-CV-12257-PBS (via Verilaw)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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U.S. DISTRICT COURT
DISTRICT OF MASS.

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)
IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION)

MDL NO. 1456

CIVIL ACTION: 1:01-CV-12257-PBS

Judge Patti B. Saris

)
)
THIS DOCUMENT RELATES TO:)

State of California, et al. v.)

Abbott Laboratories, Inc. et al.,)

CIVIL ACTION NO. 1:03-CV-11226-PBS)

**ABBOTT LABORATORIES, INC.'S RESPONSE TO THE
STATE OF CALIFORNIA'S SUPPLEMENTAL BRIEF REGARDING
REMAND AND FEDERAL PREEMPTION OF REBATE CLAIMS**

Abbott Laboratories, Inc. (“Abbott”) hereby submits this response to The State of California’s Supplemental Brief Regarding the Issue of Federal Preemption of Rebate Claims.¹

On December 12, 2003, this Court heard oral argument on the State of California and the Relator’s “Notice of Election to Dismiss Rebate Claims From the Case and Amended Memorandum of Law in Support of Motion to Remand Pursuant to the Court’s Ruling of September 18, 2003.” At that same hearing, the Court heard oral argument on the motions to dismiss Medicaid Rebate Claims in the Montana and Nevada Attorney General actions on the basis of preemption.

During the hearing, the Court raised the issue of whether it should stay ruling on California’s Amended Remand Motion pending its decision on preemption of the Medicaid Rebate Claims in Montana and Nevada. *See* 12/12/03 Tr. at 64. California agreed that the Court should first decide the preemption issue. *See id.* Since the hearing, however, the State has filed a supplemental brief regarding preemption and requested that the Court not defer ruling on its remand motion. In addition, the State has retracted its representation to the Court at the hearing that the State would not refile the Medicaid Rebate Claims if the Court were to remand. The State has now made clear that it intends to pursue the Medicaid Rebate Claims in a separate action. Abbott briefly responds.²

I. THE STATE OF CALIFORNIA ADMITS THAT IT INTENDS TO REFILE THE MEDICAID REBATE CLAIMS

At the December 12 hearing, the Court expressed its concern that the State intended to pursue its Medicaid Rebate Claims if the Court were to dismiss those claims and grant remand of

¹ Co-defendants Wyeth Inc. and Wyeth Pharmaceuticals Inc. (collectively, “Wyeth”) have authorized Abbott to state that they concur in this response.

² The information contained in this response has previously been revealed in pleadings filed by California and served on all parties via Verilaw. In addition, the preemption issues relate directly to Defendants’ Motion to Dismiss the Montana and Nevada Complaints. Accordingly, Abbott has not filed this brief under seal.

the remaining claims. *See* 12/12/03 Tr. at 62-63. The Court also voiced its concern over the State's transparent forum-shopping (*see id.*), since manipulative tactics of the sort employed by the State here are a reason for the Court to exercise supplemental jurisdiction. *See Payne*, 134 F. Supp. 2d at 584 (denying plaintiffs' motion to remand where plaintiff engaged in manipulative tactics); *Naragon v. Dayton Power & Light Co.*, 934 F. Supp. 899, 902 (S.D. Ohio 1996) (denying motion to remand where plaintiff engaged in forum manipulation). In response, the State reassured the Court that it had "*absolutely no intention* of refiling these claims in a way that will end up in this court again." 12/12/03 Tr. at 63 (emphasis added).

That representation has now been retracted. In a footnote to its supplemental brief, the State announces that it plans to engage in exactly the manipulative tactics that concerned the Court:

Contrary to what may have been intimated by the California Attorney General's Office at the hearing on December 12, 2003, California *does intend to reserve its rights to assert its claims of rebate fraud in a separate action*, consistent with what it believes are its legitimate rights as a plaintiff in determining what claims to bring and in what court. *California has no intention of turning its rebate fraud claims over to HHS.*

Supp. Br. at 2 n.1 (emphasis added); *see also* Supp. Br. at 2 ("[I]f California determines that there are [Medicaid rebate] claims to be prosecuted *it does intend to assert its claims of rebate fraud in a separate action*" (emphasis added)).

This is precisely the type of flagrant forum shopping that troubled the Court:

The only thing that's worrying me, is the Defendants' allegations that while you may be saying you're not pursuing them, you're in fact actively pursuing them administratively through subpoenas and other such ways . . . I'm simply wondering whether this is too close to for[u]m shop[ping], in other words, if you're just going to go back and refile in three or four months, then the whole case ends up coming right back here.

12/12/03 Tr. at 62. The State's express intention to pursue the Medicaid Rebate Claims in another action is reason enough for this Court to exercise supplemental jurisdiction. *See Boelens v. Redman Homes, Inc.*, 759 F.2d 504, 507 (5th Cir. 1985) ("tactical manipulation [by the] plaintiff . . . cannot be condoned"); *Payne*, 134 F. Supp. 2d at 584.³

II. THIS COURT SHOULD EXERCISE SUPPLEMENTAL JURISDICTION REGARDLESS OF HOW IT RULES ON PREEMPTION

The jurisdiction and preemption issues are distinct. The fact that Medicaid Rebate Claims are preempted does not deprive this Court of jurisdiction over the Price Reporting Claims. As this Court is aware, and as the parties agree, this Court has the discretion under 28 U.S.C. § 1367 to exercise supplemental jurisdiction over the Price Reporting Claims even if the Medicaid Rebate Claims are dismissed. *See Roche v. John Hancock Mut. Life Ins. Co.*, 81 F.3d 249, 256-57 (1st Cir. 1996). This is true whether the foundational federal claims are voluntarily dismissed (*see, e.g., Payne v. Parkchester North Condos.*, 134 F. Supp. 2d 582, 584 (S.D.N.Y. 2001)), or dismissed by the Court pursuant to motion. *See, e.g., Marcus v. AT&T*, 138 F.3d 46, 57 (2d Cir. 1998).

In exercising its discretion, the Court should consider three factors: (1) whether judicial economy, fairness and convenience favor exercising supplemental jurisdiction; (2) whether Plaintiffs have attempted to manipulate the forum in order to defeat federal jurisdiction; and (3) whether the state law claims are closely tied to questions of federal law. *See Abbott Opp. to Am. Mot. to Remand* at 7. As Abbott has demonstrated previously, these factors weigh heavily in favor of exercising supplemental jurisdiction over this case. *See Abbott Opp. to Am. Mot. to Remand* at 7-14; *Abbott Sur-Reply in Opp. to Am. Mot. to Remand* at 1-8.

³ The State continues to seek remand of a complaint that neither the Court nor the defendants have ever seen in full and has failed to address Defendants' argument concerning the fact that Plaintiff Ven-A-Care is in the process of transferring the Texas/Roxanne *qui tam* action to this Court under the JPML procedures. *See Abbott Sur-Reply in Opp. to Am. Mot. to Remand* at 2.

Supplemental jurisdiction is particularly appropriate here given the existence of the MDL proceedings and the opportunity to coordinate this case with other factually and legally similar actions in the MDL. *See In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 19 F. Supp. 2d 263, 269-70 (D. N.J. 1998) (exercising supplemental jurisdiction over state law claims in an action that had been transferred to an MDL proceeding, despite the dismissal of all federal claims, because economy, convenience and fairness favored coordinating that action with other factually and legally similar actions in the MDL). The Attorney Generals of Montana and Nevada have advised the Court that they want to stay in the MDL even if their Medicaid Rebate Claims are dismissed on preemption grounds. *See* 12/22/03 Letter to Court from S. Berman. Likewise, the Court should exercise supplemental jurisdiction over this factually and legally similar case regardless of whether California's Medicaid Rebate Claims are dismissed, voluntarily or otherwise.

III. CALIFORNIA'S PREEMPTION ARGUMENTS ARE INCORRECT

While the issue of Medicaid Rebate Claim preemption is premature in this case because the Medicaid Rebate Claims are still under seal and defendants have not yet moved to dismiss those claims, Abbott addresses a number of significant misstatements made by California on the preemption issue presented in the Nevada and Montana cases.

First, contrary to California's assertion (*see* Supp. Br. at 1), the states are not parties to the rebate agreements with the Secretary of HHS. That is an agreement between each participating manufacturer and HHS. *See* 42 U.S.C. § 1396r-8(a)(1); *see also* 56 Fed. Reg. 7049 (Feb. 21, 1991) (model HHS rebate agreement). Second, California erroneously contends that the preemption issue is "largely driven by the confidentiality provision" under which the states do not receive the best price data submitted by each participating manufacturer to HHS. *See* Supp. Br. at 9. While the fact that the states do not receive the best price data certainly supports

the preemption analysis, the preemption issue as presented in the Montana and Nevada cases is driven by the fact that the states are attempting to litigate a fraud-on-a-federal-agency claim that turns on the meaning of terms in contracts with the federal government to which the states are not parties.⁴

Third, California contends that its Medicaid Rebate Claims “are not related to” the “federal contract” with HHS. *See* Supp. Br. at 9. This is simply not so. California claims that its best price claims are based on the allegation that various unnamed manufacturers “defrauded” the federal government by misclassifying drugs as “non-innovator drugs (subject to a lower rebate) rather than innovator drugs (subject to higher rebates).” *See* Supp. Br. at 8. Significantly, the question of whether particular drugs should be classified as non-innovator or innovator drugs for purposes of the Medicaid rebate statute turns *entirely* on federal law; California law and California’s Medicaid plan are silent on this issue. Terms such as “innovator” and “non-innovator” are defined explicitly in the HHS Medicaid rebate agreement and the rebate statute and have been the subject of Medicaid rebate “program releases” issued by CMS. *See* 56 Fed. Reg. 7049; 42 U.S.C. § 1396r-8(k)(7); *HCFA/CMS Medicaid Drug Rebate Program Release No. 55* at 2 (Oct. 5, 1995); *HCFA/CMS Medicaid Drug Rebate Program Release No. 71* (Nov. 20, 1997) (attached as Exhibits 2 and 3, respectively, to Defendants’ Consolidated Memorandum in Support of Defendants’ Motion to Dismiss the State of Montana’s and the State of Nevada’s Amended Complaints).⁵

⁴ California asserts that the Medicaid Rebate Claims are not “explicitly preempted” by the rebate statute, but the defendants in the Nevada and Montana cases never argued otherwise.

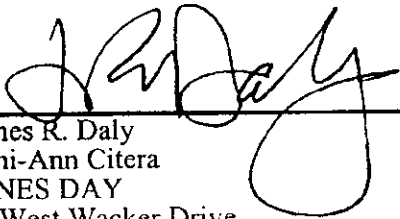
⁵ California quotes a provision from the Medicaid Act permitting states to investigate “any aspect of the provision of medical assistance and the activities of providers of such assistance *under the Medicaid State plan*” (*see* 42 USC 1396b(q) (emphasis added)), but there is *nothing* in California’s State Medicaid plan about how to classify drugs for purposes of submitting the Medicaid rebate best price reports to the federal government.

Finally, California remarkably contends that the “federal government will not represent the state’s claims in regard to Medicaid fraud.” *See* Supp. Br. at 5. But in *each* of the best price federal investigations cited in the Montana and Nevada complaints (*see* Montana Second Am. Compl., ¶¶ 272, 324, 510, 617; Nevada Am. Compl. ¶¶ 217, 331 (citing recent best price settlements involving AstraZeneca, Bayer, GSK and Pfizer)), many states (including California in at least one case) obtained their Medicaid share of the settlement even though it was the Department of Justice that handled those investigations under federal law. *See, e.g.*, Exhibit A (settlement between GlaxoSmithKline and State of California). Thus, contrary to the “general experience” of one of California’s lawyers (*see* Temmerman Decl., ¶ 2), the states have been able to recover their Medicaid share in these federal best price investigations.

CONCLUSION

For the foregoing reasons and the reasons stated in Abbott's Memorandum and Sur-Reply in Opposition to the State of California's and Relator's Amended Remand Motion, this Court should deny the Amended Remand Motion and exercise supplemental jurisdiction over this case.

Dated: January 9, 2004



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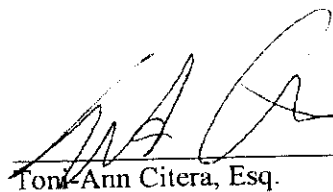
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***Counsel for Defendant Abbott Laboratories,
Inc.***

CERTIFICATE OF SERVICE

I hereby certify that on January 9, 2004, I, Toni-Ann Citera, an attorney, caused a true and correct copy of the foregoing **Abbott Laboratories, Inc.'s Response To The State Of California's Supplemental Brief Regarding Remand And Federal Preemption Of Rebate Claims** to be served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by transmitting a copy to Verilaw Technologies for posting and notification to all parties.

By:

A handwritten signature in black ink, appearing to read 'Toni-Ann Citera', is written over a horizontal line.

~~Toni-Ann Citera, Esq.~~

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